


MEMORANDUM

DATE: December 8, 1999

TO: Tom Bell, Mohandas Bhat, Frank Hawkins, Ruth Neta, Joe Weiss, and Libby White

FROM: Barrett Fountos 

SUBJECT: Summary of the November 15-16, 1999 Joint Meeting of Ukrainian and NCI Working Groups on Leukemia in Chernobyl Cleanup Workers

The National Cancer Institute's (NCI) Division of Cancer Epidemiology and Genetics sponsored a binational meeting at the Bethesda Pooks Hill Marriott to review the results of Phase I and discuss whether to conduct Phase II of the leukemia study. Dr. Gil Beebe chaired the meeting. The Ukrainian delegation was led by Dr. Anatoly Romanenko. Please see the attached participant list for other attendees.

After a presentation on the results of the Phase I study, the Working Group decided to modify the Phase II study in several ways. First, the study design will now be case-control rather than case-cohort. Four hundred fifty cases are expected. Cases will be males registered in the Ukrainian Chernobyl State Registry as a cleanup worker between 1986-1990, whose date of registration was within 2 years after completion of service, who was born between 1926 and 1970, and who was first diagnosed between 1987 and 2001. Workers from the following oblasts will be included: Cherkaskaya, Chernihivskaya, Dnipropetrovskaya, Kharkivskaya, Kievskaya, and Kiev City. Based on the poor response in the pilot study, workers from the following oblasts will be excluded: Donetskaya, Sumskaya, and Poltavskaya.

There was considerable debate about which diseases besides leukemia should be included in Phase II. Although the evidence for leukemia following exposure to ionizing radiation is clear, the evidence for lymphoma and multiple myeloma is contradictory. If there is a risk from these diseases, then Dr. Howe suspects it will be much lower than for leukemia. In that case, there will even be less statistical power to detect these diseases. Therefore, Dr. Howe did not believe that there was a strong rationale for including these two diseases in Phase II. Nevertheless, the Working Group decided that the diseases to be studied are: leukemia, multiple myeloma, and myelodysplasia.

The dosimetry in Phase I was considered inadequate. The Phase I study did not address the validity of official dose records in that there was no systematic assessment of quality, did not assess uncertainties, and did not evaluate target tissue doses (bone marrow). The Working Group decided to rely on physical dosimetric methods, such as electron paramagnetic resonance (EPR), analytical dose reconstruction (ADR) and soft expert assessment of dose (SEAD).

It was decided that the 1996 protocol will be discarded and a new proposal will be prepared by Geoffrey Howe, Andre Bouville, Stuart Finch, Dmitry Bazyka, Victor Klimenko, Vadim Chumak, and Boris Ledoshchuk.

NCI management intends to decide whether to proceed with a modified Phase II study by the end of December 1999.

National Cancer Institute
Division of Cancer Epidemiology and Genetics

**Joint Meeting of Ukrainian and NCI Working Groups
on
Leukemia in Chornobyl Cleanup Workers**

Bethesda Marriott-Pooks Hill, Bethesda, Maryland
November 15-16, 1999

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National Cancer Institute
Division of Cancer Epidemiology and Genetics

**Joint Meeting of Ukrainian and NCI Working Groups
on
Leukemia in Chernobyl Cleanup Workers**

Bethesda Marriott-Pooks Hill, Bethesda, Maryland
November 15-16, 1999

**PRELIMINARY AGENDA
Monday, November 15**

8:30am – 9:00am *Continental Breakfast*

Meeting Co-Chairs: Dr. Beebe and Dr. Romanenko

9:00am – 9:15am Welcome, Introductory Remarks

Dr. Hoover

9:15am – 10:15am I. Purpose of the Meeting

- A. Changes in the Draft Final Report on Phase I
- B. What a Modified Phase II Protocol Might
 Contain
- C. Whether we Recommend a Modified Phase II

10:15am – 10:30am *Coffee Break*

10:30am – 12:30pm II. Review of Final Report, Phase I

- A. Changes Suggested by the Research Center
 for Radiation Medicine (The "Center"):
 - 1. Epidemiology
 - 2. Hematology
 - 3. Dosimetry

Dr. Ledoshchuk
Dr. Klimenko
Dr. Chumak &
Dr. Pilinska

- B. Discussion of Suggested Changes

12:30pm – 1:30pm *Lunch*

1:30pm – 3:15pm III. Presentation of Plans for Modified Phase II Study

A. Plan Suggested by the Center

1. Epidemiology
2. Hematology
3. Dosimetry

Dr. Ledoshchuk
Dr. Klimenko
Dr. Chumak &
Dr. Pilinska

3:15pm – 3:30pm *Coffee Break*

3:30pm – 5:00pm B. Comparison of Center Plan and Plan of
NCI Working Group

C. Discussion

5:00pm – 6:00pm *Open Period*

6:00pm – 8:30pm Dinner (by invitation only)
Bethesda Marriott – Pooks Hill

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**PRELIMINARY AGENDA
Tuesday, November 16**

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|--------------------------|---|
| 8:30am – 9:00am | <i>Continental Breakfast</i> |
| 9:00am – 10:15am | Reaching Consensus on Recommendation as to
Phase II
General Discussion |
| 10:15am – 10:30am | <i>Coffee Break</i> |
| 10:30am – 12:30pm | General Discussion Continued |
| 12:30pm – 1:30pm | <i>Lunch</i> |
| 1:30pm – 3:45pm | Subsequent Steps To Be Taken Following Achievement of Consensus:

(only if our recommendation is favorable and NCI supports continuation)

<ol style="list-style-type: none">1. Revision/Editing Final Report on Phase I as Supporting Document for the Proposal2. Writing a New Proposal Suitable for Review by Ukraine and NCI3. Submittal of New Proposal for Review by Responsible Authorities for Ukraine and by NCI |
| 3:45pm – 4:00pm | Closing |

